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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,038	01/23/2002	Antonio Verdini	0558-4024	1685

7590 03/18/2004

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EXAMINER	
WAX, ROBERT A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/048,038	<b>Applicant(s)</b> VERDINI, ANTONIO	
	<b>Examiner</b> Robert A. Wax	<b>Art Unit</b> 1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 and 48-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-20 is/are allowed.
- 6) ☒ Claim(s) 1-11, 21-35 and 48-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>01232002</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Priority***

1. The current application filed on January 23, 2002 is a 371 of PCT/EP00/07022 filed on July 21, 2000, which in turn claims priority to Italian application, F099A000015 filed on July 23, 1999.

### ***Information Disclosure Statement***

2. The information disclosure statement filed January 23, 2002 has been considered. Please see the attached initialed PTO-1449.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-11, 21-35 and 48-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, under the definition of "p" the term "irradiating" should be "radiating"; in claim 2, "n" is never defined; in claim 3 the meaning of "i=3,4" is unclear; in claim 4, "m" is never defined; in claim 5 the term "repres nted" obviously should be "represented", further in claim 5 the term "aminoacid" should be "amino acid" and "5 or 6 atoms ring"

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should read "5- or 6-atom ring"; in claim 10 the term "aminoacid" should be "amino acid" (the term appears twice); in claims 21 and 25 it is unclear to what "the same" refers; in claims 22, 23, 26, 27, 49, 50 and 51 the phrase "selected in the group comprising" is ambiguous and should read, "selected from the group consisting of"; in claims 22, 26 and 50 the term "aminoacid" should be "amino acid"; in claim 49 the term "aminoacids" should be "amino acids". Those claims not specifically named in the above paragraph are included in the rejection because they depend from a rejected claim and do not cure the defect.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 5, 6, 9, 11, 21-24, 31, 32 and 48-51 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Huang et al. (Mol. Immunol. Vol. 31, No. 15, pp. 1191-1199, 1994).

As stated in the International Preliminary Examination Report, Huang et al. teach polypeptide dendrimers having symmetrical extensions and their use for medical purposes. The multifunctional core moiety may be lysine, which has two NH<sub>2</sub> groups, rendering it multifunctional. Claims 5 and 6 are included because the specified

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parameters for "L" read on polylysine. Claim 9 is included because "p" would be 2 in Huang et al. Claim 11 is included because the dendrimers of Huang et al. must inherently be in the size range recited. The marker molecule mentioned in claims 21-24 and 48-51 would be the antigens disclosed by Huang et al. Some of these antigens "elicit CTLs capable of killing syngeneic cells expressing gp120 on their surfaces." This constitutes therapy.

These teachings clearly anticipate the above claims.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 25-30 and 48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al. in view of Kim et al. (Current Opinion in Chemical Biology (Dec. 1998,) Vol. 2, No.6, pp. 733-742) and prior art admissions in the instant specification.

The teachings of Huang et al. are outlined above. Huang et al. do not entrapment of treatment or detection agents within the dendrimer.

Kim et al. teach the use of peptide dendrimers as drug delivery vehicles and pharmaceuticals, see page 738, left column, near the end of the first paragraph.

The instant specification discusses known uses for dendrimers in general at pages 1-4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the peptide dendrimers of Huang et al. as pharmaceuticals or drug delivery vehicles with the expectation of achieving the beneficial results taught by Kim et al. and outlined in the instant specification.

#### ***Allowable Subject Matter***

9. Claims 2, 3, 4 and 7-10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

10. Claims 12-20 are allowed. The prior art of record neither teaches nor suggests peptide dendrimers having the exact formulae of these claims.

#### ***Conclusion***

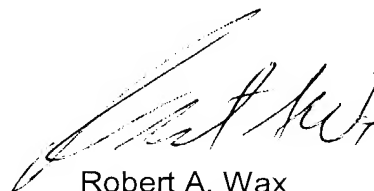
11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure because these references disclose dendrimers and methods of making them.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Robert A. Wax', is positioned above the printed name and title.

Robert A. Wax  
Primary Examiner  
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